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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/639,289 08/15/00 DEDHIYA

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EXAMINER

WELLS, J.

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/639,289	Applicant(s) DEDHIYA ET AL.	
	Examiner Lauren Q Wells	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "relative volumetric ratios amounts" in claim 1 is a relative term which renders the claim indefinite. The term "relative volumetric ratio amounts" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(ii) Claims 2-4 are vague and indefinite, as it is not clear what the mL is referring to. Does it refer to mL of the composition or mL of the semiaqueous solvent or mL of something else?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (5716638) in view of Peart et al. (WO 00/24362) and Vachon (XP-000965573) in further view of Allison's Apothecary.

Touitou teaches medical compositions for topical application to the skin. Disclosed is a composition comprising 7uci/ml tetrahydrocannabinol, 49% ethanol, 19.6% propylene glycol, and 29.4% water, which meets claims 1, 2, 3, 5, 6, 7. The composition particles are disclosed as having a size ranging from .01-8.2 um. The reference fails to teach dosages, preferred ratios of propylene glycol, and aerosols.

Peart et al. teach therapeutic formulations for solutions of delta 9 tetrahydrocannabinol. It is disclosed that a wide variety of solvents, such as ethanol and propylene glycol may be used in preparations of the solutions. The optimal size of the aerosolized droplets is disclosed as being less than 10 um. Further disclosed is a metered dose inhaler comprising a housing, a metering valve connected to housing, and an aerosol composition comprising delta 9 tetrahydrocannabinol.

Vachon et al. teach the airways response to aerosolized delta 9 tetrahydrocannabinol. The vehicle of the composition is disclosed as propylene glycol and water in a ratio of 9:1. The concentration of tetrahydrocannabinol is disclosed as 4.5g/100 ml.

Allison's Apothecary teach amber glass bottles that come with an atomizer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the invention of Touitou with the teachings of Peart et al. and obtain an aerosolized composition because a) Touitou and Peart et al. both teach composition

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comprising tetrahydrocannabinol for therapeutic use; b) Touitou and Peart et al. teach composition particles of similar sizes. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references by using the teachings of Vachon et al. and obtain a higher ratio of propylene glycol in the solvent system because a) Touitou and Peart et al. all teach compositions comprising tetrahydrocannabinol as the active agent; b) Touitou and Peart et al. teach propylene glycol as solvents; c) Vachon et al. teach that increasing the propylene glycol:water ratio increases the clarity of the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of the combined references with that of Allison's Apothecary and obtain a multi-dosage form container comprising Type I Amber Glass because a) Vachon et al. teach administration via a multi dosage nebulizer; b) Peart et al. teach that that containers for the formulations of the instant invention may be any that are suitable for the efficacious delivery of aerosol inhalants and that have various dose metering chambers.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 10, 2001


DAMERON L. JONES
PRIMARY EXAMINER